

Application Number 10/731,869
Response to final Office Action mailed June 20, 2008

REMARKS

This submission is responsive to the final Office Action dated June 20, 2008. Claims 1–31 and 33–61 are pending.

Claim Rejection Under 35 U.S.C. §§ 102(e) and 103(a)

In the final Office Action, claims 1–4, 6–9, 11–25, 27–30, 33–49, 51–54, 56, and 58–61 were rejected under 35 U.S.C. § 102(e) as being anticipated by Berrang et al. (U.S. Patent No. 6,358,281, hereinafter “Berrang”). Claim 55 was rejected under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Berrang. In addition, claims 5, 10, 26, 31, 50 and 57 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Berrang.

Applicant respectfully traverses the rejection of the claims. Berrang fails to disclose each and every feature of the claimed invention, and provides no teaching that would have suggested the desirability of modification to include such features.

Independent Claims

Berrang fails to teach or suggest an implantable medical device comprising a first module that includes control electronics within a first housing, a second module that includes a second housing, and an overmold that at least partially encapsulates the first and second housings, where the first and second housings are coupled, and the coupling of the first and second housings allows the housings to have a plurality of degrees of freedom of movement relative to each other, as recited by Applicant’s independent claim 1.

In support of the rejection of independent claim 1, the Office Action found that “Berrang et al. discloses a first and second modules [sic] disposed within corresponding first and second housing [sic] in addition to the pliable (or bendable) bridge, which the examiner considers to be an overmold” and referenced FIG. 1 of Berrang.¹ The Office Action characterized housing sections 2 and 3, which are also shown in FIGS. 2 and 3 of Berrang, as modules that have respective housings encapsulated by an overmold.² Applicant respectfully disagrees with the

¹ Office Action at page 6, item 1.

² Office Action at page 6, item 1.

Application Number 10/731,869
Response to final Office Action mailed June 20, 2008

Office Action's characterization of the housing sections 2, 3 of Berrang as first and second modules each comprising a housing, as required by Applicant's claim 1, and the characterization of the bridge 6 as an overmold that at least partially encapsulates housings of the housing sections 2, 3.

Applicant maintains that Berrang clearly and repeatedly describes its device as having a single housing ("the housing") comprising two sections.³ At no time does Berrang teach or even suggest that its device includes at least a first module comprising a first housing and a second module comprising a second housing, much less an overmold that at least partially encapsulates the first and second housings, as recited by Applicant's independent claim 1.

In the Response to Arguments section, the Office Action asserted that because Berrang discloses that the housing of its device includes two sections, Berrang discloses first and second housings.⁴ Applicant respectfully disagrees with this assertion. Berrang discloses a device comprising a single housing that contains the electronics, battery, and so forth.⁵ The housing sections 2, 3 disclosed by Berrang are merely two different regions of the housing. Berrang in no way suggests that each of the housing sections 2, 3 each comprise a respective housing. The Office Action failed to provide any support for an assertion that the housing sections 2, 3 necessarily comprise respective housings.

Given the lack of discussion in Berrang of a device comprising two housings and the explicit disclosure by Berrang of a device having a single housing, the Office Action appears to be relying on an improper finding of an inherent disclosure to support the assertion that the housing sections 2, 3 comprise respective housings. The fact that a certain characteristic may be present in the prior art is not sufficient to establish the inherency of that result or characteristic.⁶ The Office Action must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.⁷ No reasonable support has been provided for the Office Action's

³ Berrang, at col. 3, l. 25 – col. 4, l. 4 and col. 9, ll. 51–62.

⁴ Office Action at p. 2.

⁵ Berrang at col. 3, ll. 26–30.

⁶ *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ.2d 1955, 1957 (Fed. Cir. 1993); MPEP § 2112.

⁷ *Ex parte Levy*, 17 USPQ.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original); MPEP 2112.

Application Number 10/731,869
Response to final Office Action mailed June 20, 2008

assertion that housing sections 2, 3 necessarily comprise respective housings. Applicant submits that the allegedly inherent characteristic does not necessarily flow from the teachings of Berrang.

Berrang does not contemplate an arrangement in which the bridge 6 at least partially encapsulates first and second housings of first and second modules, respectively. While the Office Action discusses the elements of Berrang that it considers to be first and second modules, the Office Action failed to provide an indication of the elements of the Berrang device that the Office Action considers to be housings of the modules. Berrang fails to teach or even suggest that the housing sections 2, 3 may include separate housings. For example, even though at column 11, lines 60–63, Berrang teaches the use of a medical grade epoxy (or any biocompatible polymer) 28 to coat and encapsulate the internal components (mounted on the ceramic substrates 24 and 25) of the housing sections 2, 3, the epoxy does not define a housing for each the housing sections 2, 3.

Berrang specifically discloses that the outside edges of the ceramic substrates 24 and 25, or the areas over the snap domes 20 and 23 are not coated by the epoxy.⁸ Thus, the epoxy surfaces are not housings for elements 2 and 3, because the epoxy surfaces in no way house elements 2 and 3 as required by a housing. Rather, the epoxy surfaces are merely components of elements 2 and 3. The housing sections 2 and 3 of Berrang share a housing (i.e., the gold layer), and in no way have respective first and second housings, as required by Applicant's independent claim 1.

Furthermore, the bridge 6 of the Berrang device is not an overmold as asserted by the Office Action. Berrang discloses that the housing sections 2, 3 are connected by a bridge 6, which comprises a pliable metal.⁹ It is unclear how this bridge 6 is an overmold that at least partially encapsulates first and second housings of respective modules. In the Response to Arguments section, the Office Action asserted that FIGS. 2 and 4 of Berrang illustrate a bridge 6 that at least partially encapsulates two housing sections 2, 3.¹⁰ Applicant respectfully disagrees. Even if the housing sections 2, 3 are modules, an assertion with which Applicant disagrees, FIGS. 2 and 4 do not illustrate a bridge 6 that at least partially encapsulates housings of the housing sections 2, 3. FIGS. 2 and 4 appear to illustrate a bridge structure 6 that is merely

⁸ Berrang at col. 11, lines 60–63.

⁹ Berrang at col. 9, ll. 51–54.

¹⁰ Office Action at p. 2.

Application Number 10/731,869
Response to final Office Action mailed June 20, 2008

adjacent to housing sections 2, 3. Nothing shown within FIGS. 2 and 4 or disclosed within the Berrang detailed description suggests that the bridge 6 at least partially encapsulates housings of the housing sections 2, 3.

The Office Action further stated that column 9, lines 58–62 of Berrang teaches that “the housing sections 2 and 3 and bridge structure 6 are preferentially coated with gold, and, in a further embodiment, further coated with titanium, platinum, medical grade silicone, or any combination thereof.”¹¹ In the Response to arguments, the Office Action clarified that the Examiner does not consider the gold to be the overmold itself, but to be “merely incorporated into the overmold.”¹² Applicant respectfully disagrees that the gold coating the bridge structure 6 is “incorporated” into the bridge structure 6. Berrang does not provide any support for the assertion that the gold coating is incorporated into the bridge structure 6. Instead, Berrang merely states that the bridge structure, as well as the housing sections 2, 3 are coated with the gold. Thus, the gold and bridge structure 6 appear to be separate components of the Berrang device and the gold cannot reasonably be characterized as being “incorporated” into the bridge structure 6 such that the bridge structure comprises at least two materials, as asserted by the Office Action.

For the reasons discussed above with respect to Applicant’s independent claim 1, Berrang fails to teach or suggest an implantable medical device comprising a first module that includes control electronics housed within a first housing, a second module that includes a power source that provides power to the first module housed within a second housing, an interconnect member that flexibly couples the first and second housings, where the interconnect member is flexible in a plurality of directions and allows the first and second modules to have a plurality of degrees of freedom of movement relative to each other, and a flexible overmold that at least partially encapsulates the first and second housings, as recited by Applicant’s independent claim 23.

Similarly, Berrang fails to teach or suggest each and every element of Applicant’s independent claim 39. Claim 39 recites an implantable medical device that comprises a first module that includes control electronics housed within a first housing, a second module that includes a power source that provides power to the first module housed within a second housing,

¹¹ Office Action at page 6, item 1.

¹² Office Action at p. 2.

Application Number 10/731,869
Response to final Office Action mailed June 20, 2008

and a hermetic interconnect member that flexibly couples the first and second housings, where the interconnect member is flexible in a plurality of directions and allows the first and second modules to have a plurality of degrees of freedom of movement relative to each other. In addition to the first and second modules comprising respective housings, Berrang fails to teach or suggest a hermetic interconnect member. The Office Action asserted that "the pliable bridge unites the two housings and as a result acts as a hermetic interconnect member."¹³ Applicant respectfully disagrees. Berrang fails to disclose or even suggest that the bridge structure 6 is hermetic. The Office Action offered absolutely no support for this assertion.

Applicant's independent claim 42 is directed toward an implantable medical device that comprises a first module comprising control electronics and a therapy delivery circuit housed within a first housing, a second module comprising a power source within a second housing, an interconnect member that flexibly couples the first and second modules and includes a conductor for delivery power from the power source to the control electronics and the therapy delivery circuit, and a flexible overmold that at least partially encapsulates the first and second housings. As discussed above with respect to independent claim 1, Berrang fails to teach or suggest at least first and second modules each comprising a respective housing, as well as an overmold that at least partially encapsulates the first and second housings. For at least these reasons, Applicant's independent claim 42 is patentable over Berrang.

Berrang also fails to teach or suggest each and every element of Applicant's independent claim 56 as amended. Claim 56 is directed to an implantable medical device that comprises a first module comprising control electronics within a first housing, a second module comprising a recharge coil within a second housing, a third module comprising a rechargeable power source within a third housing, an overmold that at least partially encapsulates the first and third housings, and a flexible tether member that connects the overmold and the second housing. Berrang does not teach or suggest such elements, much less an arrangement in which control electronics and a rechargeable power source are provided in separate housings that are at least partially encapsulated by an overmold, and a recharge coil is provided within another housing that is connected to the overmold. Furthermore, the Office Action fails to point out how Berrang

¹³ Office Action at p. 2.

Application Number 10/731,869
Response to final Office Action mailed June 20, 2008

anticipates such an arrangement of the control electronics, rechargeable power source, and recharge coil.

Dependent Claims

Claims 2–22 and 58 depend from claim 1, claims 24–31, 33–38, and 59 depend from claim 23, claims 40 and 41 depend from claim 39, claims 43–55 and 60 depend from claim 42, and claims 57 and 61 depend from claim 56. Claims 2–22, 24–31, 33–38, 40, 41, 43–55, and 57–61 are patentable over Berrang for at least the reasons provided above with respect to independent claims 1, 23, 39, 42, and 59. In addition, the dependent claims recite additional elements that are neither disclosed nor suggested by the cited art. Applicant addresses some of the dependent claims below for purposes of illustration.

Claims 5, 26, and 45 specify that the implantable medical devices of claims 1, 23, and 42, respectively, each include a recharge coil located within the overmold, where the recharge coil substantially encircles the first and second modules. In support of the rejection of claims 5 and 26, the Office Action acknowledged that Berrang fails to disclose or suggest the recharge coil of claim 5, but asserted that claim 5 would have been obvious in view of Berrang because “it has been held that rearranging parts of an invention involves only routine skill in the art.”¹⁴ Applicant respectfully disagrees with this conclusion of obviousness.

Berrang discloses a coil 4 that may be used to recharge a battery 18 housed within a housing section 2 of its device.¹⁵ As shown in FIG. 1 of Berrang, the coil 4 does not substantially encircle the housing sections 2, 3, which the Office Action characterized as modules. Modification of the Berrang device to position the coil 4 around the housing sections 2, 3 requires more than just a rearrangement of parts. For example, as shown in FIG. 1, the coil 4 has a smaller diameter than the perimeter substantially encircling the housing sections 2, 3. Thus, the modification proposed by the Office Action would require changing the shape and size of the coil 4. Berrang does not provide any suggestion that such a modification to the coil 4 would be useful or would even render the coil 4 useful for its intended purpose.

¹⁴ Office Action at p. 8, item 2.

¹⁵ Berrang at col. I2, ll. 50–54.

Application Number 10/731,869
Response to final Office Action mailed June 20, 2008

Moreover, Berrang discloses that an "inventive feature" of its device is the location of the coil 4 away from interfering metal materials, which, according to Berrang, improves the inductive power coupling efficiency across a skin surface with an external coil.¹⁶ Berrang provides absolutely no basis for concluding that positioning the coil 4 such that it substantially encircles the housing sections 2, 3 would maintain this feature of the Berrang disclosure.

The Office Action has also failed to identify a motivation or a reason that a person skilled in the art would have modified the Berrang device to substantially encircle the housing sections 2, 3 with the coil 4. "The mere fact that a worker in the art could rearrange the parts of the reference device to meet the terms of the claims . . . is not by itself sufficient to support a finding of obviousness."¹⁷ The prior art must provide a motivation or a reason for the modification. Absent access to Applicant's disclosure, there is no apparent reason why one having ordinary skill in the art would have modified Berrang in the manner proposed by the Office Action.

Claims 6 and 27 specify that the implantable medical devices of claims 1 and 23 each include a third module that includes a third housing that houses a recharge coil. The Office Action asserted that FIG. 1 of Berrang illustrates a housing that houses the coil 4.¹⁸ Applicant respectfully disagrees. Berrang does not disclose or suggest that the coil 4 is housed in a housing, and FIG. 1 does not illustrate a housing.

The Office Action asserted that claims 7 and 9 were anticipated by Berrang. Claim 7 specifies that the overmold at least partially encapsulates the third module that includes the third housing that houses the recharge coil. Claim 9 specifies that the third module is located outside of the overmold and a flexible tether member connects the third module to the overmold. It is unclear how the coil 4 disclosed by Berrang can be at least partially encapsulated by the bridge structure and located outside of the overmold, as the Office Action appears to be suggesting. Clarification of the rejection of claims 7 and 9 is respectfully requested.

Claims 28, 30, 47, and 49 were also rejected as being anticipated by Berrang. Claims 28 and 47 specify that an overmold at least partially encapsulate a third module that includes a third housing that houses a recharge coil. Claims 30 and 47 specify that the third module is located outside of the overmold. Just as with claims 7 and 9, it is unclear how the coil 4 disclosed by

¹⁶ Berrang at col. 10, ll. 35-39.

¹⁷ MPEP 2144.04(VI)(C).

¹⁸ Office Action at p. 6, item 1.

Application Number 10/731,869
Response to final Office Action mailed June 20, 2008

Berrang can be at least partially encapsulated by the bridge structure and located outside of the overmold, as the Office Action appears to be suggesting. Clarification of the rejection of claims 28, 30, 47, and 49 is respectfully requested.

Claim 11 specifies that the overmold of claim 1 completely encapsulates the first and second modules. Berrang fails to disclose or suggest an overmold that completely encapsulates the first and second modules. The Office Action characterized the bridge 6 of the Berrang device as an overmold and stated that the bridge s 6 “partially encapsulates the . . . first and second housing [sic].”¹⁹ Claim 11, on the other hand, requires an overmold that completely encapsulates first and second modules. The Office Action failed to address this requirement of claim 11. As provided in 37 C.F.R. 1.104(c)(2), the Examiner must designate the particular part of a reference as nearly as practicable. However, with respect to claim 11, as well as many of the other dependent claims, the Examiner has failed to do so. Thus, on at least the basis that the Office Action failed to meet the burden of demonstrating that Berrang discloses every element of claim 11, Applicant respectfully requests clarification of the rejection of independent claim 11 or withdrawal of the rejection.

Claim 19 specifies that the implantable medical device of claim 1 further comprises a lead connection module formed within the overmold to receive one of a lead that includes an electrode and a lead extension that is coupled to the lead, and a conductor that extends from the lead connection module to the first module, where the first housing comprises a hermetic feedthrough to receive the conductor and the conductor electrically couples the electrode to the first module. The Office Action asserted that Berrang discloses each and every element of claim 19. However, Berrang fails to disclose, among other things, a first housing that comprises a hermetic feedthrough. The Office Action asserted that the Berrang device includes a lead connection module “between the bridge 6 and the lead junction 16.” Even if this is true, an assertion with which Applicant disagrees, Berrang fails to disclose that the housing section 3 (the “first module” according to the Office Action) includes a hermetic feedthrough that receives a conductor.

Berrang discloses that the internal components of the housing section 3 are mounted to a ceramic substrate 25, which contains a plurality of electrically insulated electrical lead-

¹⁹ Office Action at p. 6, item 1 (emphasis added).

Application Number 10/731,869
Response to final Office Action mailed June 20, 2008

throughs.²⁰ Even if the lead-throughs disclosed by Berrang are feedthroughs that receive a conductor, Berrang fails to disclose that the lead-throughs are hermetic. Moreover, it does not necessarily follow that the lead-throughs are hermetic. Accordingly, Berrang fails to disclose or suggest each and every element of claim 19.

Claim 34 states that the interconnect member of the medical device of independent claim 23 is hermetic and defines at least one lumen between the housings of the first and second modules. While the Office Action asserted that claim 34 was anticipated by Berrang, the Office Action failed to describe or point to a lumen in the bridge 6 of the Berrang device, which the Office Action characterized as a “interconnect member.” Berrang fails to disclose or suggest that the bridge 6 includes a lumen between the housings of the first and second housing sections 2, 3, which the Office Action characterized as “modules.” Berrang discloses that the bridge structure 6 comprises a pliable metal. As shown in FIG. 2 of Berrang, the bridge 6 does not appear to define a lumen that extends between the housing sections 2, 3, and, instead, appears to comprise a solid structure. Berrang also fails to disclose or suggest that the bridge 6 is hermetic.

Clarification of the rejection of claim 34 is respectfully requested.

Claims 58–61 each specify that at least one of the housings of the modules of a medical device comprises a hermetic housing. As an initial matter, Applicant notes that the Office Action failed to specifically address the requirements of Applicant’s claims 58–61 and failed to provide any explanation of how Berrang discloses each and every element of claims 58–61. Clarification of the rejection of claims 58–61 is respectfully requested.

Berrang fails to disclose or suggest the requirements of claims 58–61. The Office Action reasoned that housing sections 2 and 3 were modules. However, the sections 2 and 3 do not have separate housings, and Berrang specifically states that the epoxy that is used to coat and encapsulate the internal components of elements 2 and 3 do “not provide a true hermetic or hermetic like seal.”²¹ For this reason, Berrang provides a single gold coating over the encapsulant surface.²² Thus, Berrang does not disclose or suggest a device including at least two modules comprising separate housings, where at least one of the housings comprises a hermetic housing, as recited by Applicant’s claims 58–61.

²⁰ Berrang at col. 11, ll. 45–48.

²¹ Berrang at column 3, lines 59–65.

²² Berrang at column 3, lines 59–65.

Application Number 10/731,869
Response to final Office Action mailed June 20, 2008

Berrang fails to disclose each and every limitation set forth in independent claims 1, 23, 39, 42, and 56, and the claims dependent therefrom. For at least these reasons, the Office Actions has failed to establish a prima facie case of unpatentability of Applicant's claims 1-31 and 33-61 under 35 U.S.C. §§ 102(e) and 103(a). Reconsideration and withdrawal of the rejection of claims 1-31 and 33-61 is respectfully requested.

Rejection for Obviousness-type Double Patenting

In the Office Action, claims 1-31 and 33-57 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 10/731,638 (now U.S. Patent No. 7,212,864), claims 1-14 of copending Application No. 10/730,878 (U.S. Publication No. 2004/0176816), claims 1-23 of copending Application No. 10/731,699 (U.S. Publication No. 2004/0172090), claims 1-54 of copending Application No. 10/730,873 (now U.S. Patent No. 7,242,982), claims 1-27 of copending Application No. 10/731,867 (U.S. Publication No. 2004/0176673), and claims 1, 2, and 14-16 of copending Application No. 10/731,868 (U.S. Publication No. 2004/0173221).

Applicant notes that originally-filed claims 2, 12, and 16 of copending Application No. 10/731,699 (U.S. Publication No. 2004/0172090) have been canceled. In addition, originally-filed claims 2, 7, 9, 35, 46, 48, 50, and 52 of copending Application No. 10/730,873 have been canceled. Originally-filed claim 11 of copending Application No. 10/730,878 (U.S. Publication No. 2004/0176816) has also been canceled. In addition, originally-filed claims 2, 11, and 23-27 of copending Application No. 10/731,867 have been canceled.

A Terminal Disclaimer accompanies this Response. The disclaimer is made to expedite issuance and is not intended as an admission that any claim of the present application is the same or an obvious variant of those of U.S. Patent Nos. 7,212,864 or 7,242,982, or U.S. Patent Application Nos. 10/730,878, 10/731,699, 10/731,867 or 10/731,868. This disclaimer obviates the double patenting rejections based on U.S. Patent Nos. 7,212,864 and 7,242,982, and U.S. Patent Application Nos. 10/730,878, 10/731,699, 10/731,867, and 10/731,868.

Application Number 10/731,869
Response to final Office Action mailed June 20, 2008

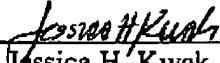
CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date: August 20, 2008

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